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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/782,543	02/18/2004	Agur Junge	117163.00102	3273
21324 7590 11/19/2007 HAHN LOESER & PARKS, LLP One GOJO Plaza Suite 300 AKRON, OH 44311-1076			EXAMINER VU, QUYNH-NHU HOANG	
			ART UNIT 3763	PAPER NUMBER
			NOTIFICATION DATE 11/19/2007	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@hahnlaw.com  
akron-docket@hotmail.com

<b>Office Action Summary</b>	Application No. 10/782,543	Applicant(s) JUNGE, AGUR	
	Examiner Quynh-Nhu H. Vu	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 18 February 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 April 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☒ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>5/13/04</u> . | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Oath/Declaration*

It does not include the inventor's signature in the declaration sheet.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10, 13, 20-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Guy et al. (US 5,334,164).

Regarding claims 1 and 21, Guy discloses a variable interior dimension cannula valve, however, it can be used as an insertion catheter, since insertion catheter are usually includes an elongate flexible tube. The device comprising: sealing element 7; a tubular main body 9 of an elastic material (col. 6, lines 63-68), a peripheral wall of the main body enclosing a hollow space that extends along a longitudinal direction of the sealing element with a connecting passage 32 for fluids; wherein the peripheral wall in the region of the connecting passage is designed in respect of elasticity of the material, thickness of the wall and inside diameter of the hollow space, such that twisting the main body causes a constriction (at 32) of hollow space in the region of the connecting passage in such a way that the constriction is at predetermined position in relation to the longitudinal direction of the sealing element (see Fig. 6-7). Examiner is taking position that if the more twisting of the body of 9, the diameter of hollow space will be reducing and the longitudinal is shorter also.

Regarding claim 2, the tubular main body 9 comprises first and second longitudinal ends (31, 33), such that twisting of the two longitudinal ends relative to each other causes regular folding of the peripheral wall in the region of the connecting passage and concomitantly therewith a reduction in the diameter of the connecting passage, which is dependent on the amount of angular twist applied (see Figs. 6-7).

Regarding claims 3-8, the peripheral wall has a smaller wall thickness in the region of the connecting passage (at 32) than in adjacent wall regions (31, 33); and the wall thickness of the peripheral wall increases steadily with increasing distance from the connecting passage. It is noted that the connecting passage is at 32.

Regarding claims 9-10, a flange 34, 35 is located at each longitudinal end of the sealing element (Fig. 9 or 15).

Regarding claim 13, the tubular main body comprises a silicon rubber (col. 6, lines 63-68).

Regarding claim 20, the connecting passage (at 32) is fully open the hollow space is of a round diameter which is substantially uniform over the longitudinal direction so that the hollow space is in the form of a cylinder open at the two ends thereof (Figs. 3-4 or 9-12).

Regarding claims 22, an insertion opening for a shaft 24, 26 (Fig. 2, 13, 15) or a surgical instrument 50 inserted into a vessel.

Regarding claims 23-28, a control element 14 retain various, rotated position after setting thereof; the control elements latch by detents 13 (col. 4, lines 51-68).

Claims 1-13, 20-28 are alternatively rejected under 35 U.S.C. 102(b) as being anticipated by Li (US 5,464,189).

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Li discloses, (Figs. 1, 4, 7, 10, 20, 30), an insertion catheter 10 comprising: a sealing element 103, a peripheral wall 118, a hollow space 109, 115, a connecting passage (at constricted or twisted, Figs. 3, 7, 10); a flange 212 (also it is well known in the art to have the flange for supporting the tubular tube), a diaphragm 218 (Fig. 20) or 512 (Fig. 30); a control element 530 (Fig. 30).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guy et al. (US 5,334,164) or Li (US 5,464,189) in view of Stevens et al. (US 5,935,112).

Guy discloses the claimed invention except for that a diaphragm which at least partially closes at least one longitudinal end of the sealing element; wherein the diaphragm has a central opening.

Stevens discloses, Fig. 2, a seal 44; a diaphragm 44 or 170 having a central opening and the diaphragm at least partially closes at least one longitudinal end of the sealing elements.

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Guy with a diaphragm, as taught by Stevens, in order to seal between the proximal end of compressible seal.

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Claims 14-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guy et al. (US 5,334,164).

Regarding claims 14-19, Guy discloses the claimed invention except for that the tubular main body comprises a material with a Shore hardness greater 30. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a tubular main body with a material of Shore hardness greater than 30, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quynh-Nhu H. Vu whose telephone number is 571-272-3228. The examiner can normally be reached on 6:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Quynh-Nhu H. Vu  
Examiner  
Art Unit 3763



Quynh-Nhu H. Vu  
SUPERVISOR  
TECHNICAL